REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

At the outset, applicant notes that the title of the invention has been revised to read "Antibodies To The Renal Nuclear Matrix Proteins, RCCA-1-5." Starting on page 26, line 20 of the specification, moreover, table 2 is revised to correct a typographical error: "kD" in the "Molecular Weight" column is being replaced with "D." The typographical error thus affected is apparent to the knowledgeable reader; hence, its correction introduces no new matter.

I. Disposition of the Claims

Amendment of claim 1 is requested. Support for the amendments can be found throughout the original specification, including the original claims. No new matter is added.

New claims 17-24 are presented. Support for these claims can be found throughout the original specification, including the original claims.

Upon entry of this response, claims 1-24 will be pending, with claims 2-16 have been withdrawn. Thus, claims 1 and 17-24 will be subject to examination on the merits.

II. Priority

A. Application Data Sheet

The Office Action requests that the Application Data Sheet (ADS) be updated to reflect the status of the priority documents. Thus, Applicants submit with this response an supplemental ADS with updated status information for the priority documents.

B. Priority Date

The Office Action states that the claims are entitled to priority date of November 17, 2003. According to the examiner, November 17, 2003 is the earliest filing date in which the application recites molecular weights of 53 kD, 32 kD, 27 kD, 20 kD, and 15 kD.

The present claims are entitled to the benefit of the earliest application to which priority is claimed, U.S. provisional application no. 60/041,860, filed April 8, 1997. Table 2 on page 26, lines 20-27 of the '860 application explicitly recite the molecular weights recited in claim 1. While the header of Table 2 states that the units are in "kD," one of skill in the art would readily recognize this is a typographical error. Applicants are correcting that typographical error presently, as indicated above. Accordingly, the present claims are entitled to the benefit of the '860 application, because the '860 application recites the same molecular weights as the present claims.

III. Information Disclosure Statement

The Office Action indicates that references lined out on the Information Disclosure Statement (IDS) filed March 8, 2004, have not been considered, because the references are no longer available with the parent applications.

Applicants will submit a new IDS shortly that cites the lined out references and provides copies of the same.

IV. Objections to the Specification

A. Title

The Office Action states that the title is not descriptive and suggests changing the title to "Antibodies The Renal Nuclear Matrix Protein, RCCA-1-5." Thus, Applicants have amended the title, as suggested by the Office Action.

B. Antecedent Basis for Claims

The Office Action states that the specification lacks antecedent basis for the claims, because the specification does not recite the molecular weights recited by the present claims.

As discussed above in Section II, Table 2 of the present specification contains a typographical error. Specifically, the term "kD" should be replaced with "D." Applicants

make this change with this amendment. Thus, the specification contains antecedent basis for the claimed subject matter.

V. Claim Rejections – 35 U.S.C. § 101

Claim 1 stands rejected as directed to allegedly non-statutory subject matter. According to the Office Action, claim 1 "does not sufficiently distinguish over an antibodies against RCCA-1-5 or an immunogenic fragment thereof as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products."

While not acquiescing in the propriety of the rejection, Applicants have amended claim 1 to recite that the antibody is "isolated." Thus, the claim does not cover naturally occurring antibodies, if any, to RCCA-1-5.

VI. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claim 1 stands rejected as indefinite for reciting "about." According to the Office Action, "[s]ince the term 'about' is not defined one cannot determine what the proteins bound by the claimed antibodies are or if the proteins are the same proteins or different proteins." Office Action at 4. Applicants respectfully traverse this ground of rejection.

The MPEP makes clear, however, that the "fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph." MPEP § 2173.05(b). A claim is not considered indefinite when one of skill in the art "would be ... reasonably apprised of the scope of the invention." *Id.* In the particular case of the use of "about," court's have routinely that its use does not render a claim indefinite. *See Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). When court's have found a claim indefinite for use of "about," there is often prior art which cannot be distinguished because of the use of "about."

Here, one of skill in the art would be readily apprised of the metes and bounds of claim 1. It is commonly understood that molecular weights and isoelectric points can vary

slightly depending on particular test conditions. Thus, one of skill in the art expects slight variations in these values. In addition, the proteins are defined by two separate numerical values, molecular weight and isoelectric point, so the proteins are not defined by only a single characteristic that is modified by "about."

The case law rejecting the use of "about" does not apply, because there is not prior art of record that teaches proteins with properties similar to those recited by the claims. Thus, one of skill in the art would be readily able to distinguish the recited proteins from the proteins known in the art.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

VII. Claim Rejections – 35 U.S.C. § 112, First Paragraph – Enablement

A. Rejection Based On Recited Proteins (Paragraph 13 of Office Action)

Claim 1 stands rejected for allegedly lack of enabling support by the specification. According to the Office Action, "[o]ne cannot extrapolate the teachings of the specification to the enablement of the claims because the molecular weight of a protein and isoelectric point does not uniquely identify a protein and is only an estimate of the protein molecular weight and isoelectric point and is subject to numerous variables that cannot be readily be predicted." Office Action at 6. Applicants respectfully traverse this ground of rejection.

The original specification contains sufficient description of the claimed invention to enable one of skill in the art to make and use it. The claimed invention is directed to an antibody "directed against" five recited proteins. The proteins are "absent in normal renal cells but present in cancerous renal cells." In addition, each of the five proteins are defined in terms of a molecular weight and isoelectric point. The specification describes precisely how to obtain these proteins. For example, page 24, line 5 to page 25, line 2 describes how to obtain the proteins from tissue, including the detailed protocol for the procedure. Page 25, line 3 to page 26, line 30 goes on to describe the procedure used to determine the molecular weights and isoelectric points of the recited proteins. This procedure includes detailed

information, such as the composition of the gels and the standards used to determine the isoelectric points. Thus, the specification describes in detail how to obtain the recited proteins. This description is more than sufficient to enable one of skill in the art to make and use the claimed invention, because it describes in detail how to obtain the recited proteins. Accordingly, one of skill in the art would be readily able to make the claimed antibodies.

The Office Action argues that "[o]ne cannot extrapolate the teachings of the specification to the enablement of the claims because the molecular weight of a protein and isoelectric point does not uniquely identify a protein and is only an estimate of the protein molecular weight and isoelectric point and is subject to numerous variables that cannot be readily be predicted." Office Action at 6. As support for this argument, the Office Action cites a number of references purportedly showing the limitations of the gel electrophoresis.

Contrary to the Office Action's arguments, molecular weights and isoelectric points are routinely used to characterize and identify proteins. While there can be some variability in molecular weights and isoelectric points determined using electrophoresis gels, that variability does not prevent those skilled in the art from isolating and identifying the proteins in question. Indeed, were the situation otherwise then it would no be common practice to compile and cross-reference electrophoretic data from numerous laboratories, thereby to annotate the field of proteomics. For example, see Babnigg & Giometti, *Nucleic Acids Research* 32: D582 – 85 (2004), and Lemkin *et al.*, *App. Theoret. Electrophoresis* 5: 55 – 72 (1995) (copies appended).

Here, any concerns about variability are obviated because the specification describes the detailed procedures for determining the molecular weights and isoelectric points. In addition, the proteins are not identified only by molecular weight or by isoelectric point. Rather, the proteins are described in terms of molecular weight, isoelectric point, and a presence in cancerous renal cells but not in normal renal cells. Thus, one of skill in the art is equipped with a number of characteristics to identify the recited proteins.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

B. Rejection Based On "Immunogenic Fragment" (Paragraph 14 of Office Action)

The examiner has raised another concern, on enablement grounds, with respect to claim 1. According to the Office Action, the specification "does not reasonably provide enablement for an antibody directed against a nuclear matrix protein or **an immunogenic fragment** thereof in a human subject." Office Action at 8 (emphasis added).

While not acquiescing in the propriety of the rejection, Applicants have amended the claims to no longer recite "an immunogenic fragment." Accordingly, this basis for rejection is vitiated.

VIII. Claim Rejections – 35 U.S.C. § 112, First Paragraph – Written Description

A. Rejection Based On Recited Proteins (Paragraph 15 of Office Action)

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description support. According to the Office Action, "the specification does not describe the RCCA- 1-5 proteins defined by their molecular weight and isoelectric point in a manner that satisfies either the *Lilly* or *Enzo* standards." Office Action at 15. Applicants respectfully traverse this ground of rejection.

As discussed above in Section VII, the specification contains an extensive description of the recited proteins. This description includes a description of how to obtain the proteins and how the molecular weights and isoelectric points can be determined. Such a description is sufficient to demonstrate possession of the recited proteins to one of skill in the art.

The Office Action cites *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. V. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) as support for its argument that the claims lack written description support. These cases do not support the Office Action's position.

First, *Lilly* and *Enzo* are factually different from the present case. In both *Lilly* and *Enzo*, the patentee was attempting to claim more than it actually possessed. More specifically, the patentee in *Lilly* was attempting to claim, *inter alia*, "vertebrate insulin

cDNA," although it had not isolated all "vertebrate insulin cDNA." Similarly, the Enzo patentee was attempting to claim probes by binding ability alone. While it had obtained some probes with the recited binding, it was attempting to claim all probes with the recited binding. Here, Applicants are not attempting to claim more than what they possessed. Specifically, claim 1 recites only proteins that Applicants isolated and characterized, as demonstrated in Table 2. On this basis, the present claims are distinguishable from the claims at issue in *Lilly* and *Enzo*. Thus, *Lilly* and *Enzo* do not lead to the conclusion that the present claims lack written description support.

Second, and related to the first point, *Lilly* and *Enzo* are distinguishable from the present case in the legal question they addressed. *Lilly* and *Enzo* both addressed written description support for a genus in which the specification listed only specific species of the genus. Here, the claims are not directed to a genus of proteins. Instead, the claims recite only five specific protein, each of which was isolated and characterized as described in the specification. Thus, the present claims do not raise the same legal issues as in *Lilly* and *Enzo*.

Third, even if the *Lilly* and *Enzo* were applied to the claims as suggested by the Office Action, the result would still be that the claims possess written description support.

The Federal Circuit stated in *Lilly* that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, **such as** by structure, formula, [or] chemical name, of the claimed subject matter **sufficient to distinguish it from other materials**." *Lilly*, 119 F.3d at 1567 (emphasis added). Thus, the written description must be "sufficient to distinguish it from other materials." Here, the specification describes the proteins in terms of isoelectric point, molecular weight, and their presence in cancerous renal cells but not normal renal cells. This description is sufficient to distinguish the recited proteins "from other materials." Thus, the requirements of *Lilly* are satisfied.

The Federal Circuit in Enzo stated that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics .... i.e., complete or partial structure, other physical and/or

chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo*, 296 F.3d at 1324 (emphasis omitted, bracketed material in original). Thus, Enzo requires a showing that the "invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics." Those "identifying characteristics" can include "physical and/or chemical properties" and "functional characteristics." Here, the recited proteins are describes in terms of a number of identifying characteristics, as discussed above. These characteristics include the physical characteristics of molecular weight and isoelectric point. In addition, the proteins are present in cancerous renal cells but not normal renal cells. Such a description shows that the "invention [was] complete."

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

B. Rejection Based On "Immunogenic Fragment" (Paragraph 16 of Office Action)

Claim 1 stands rejected an alleged lack of written-description support. According to the Office Action, the specification does not provide sufficient written description for "an immunogenic fragment." Office Action at 15.

While not acquiescing in the propriety of the rejection, Applicants have amended the claims to no longer recite "an immunogenic fragment." Thus, the amendment renders this rejection moot.

IX. Claim Rejections – 35 U.S.C. § 103

Claim 1 stands rejected over Konety *et al.*, JOURNAL OF UROLOGY 159:1359-1 363 (March 21, 1998) in view of Ausubel *et al.*, SHORT PROTOCOLS IN MOLECULAR BIOLOGY, 31d ed. 1997, Electroelution of Proteins from Stained Gels, p. 10133- 10135. Applicants respectfully traverse this ground of rejection.

Konety is not prior art to claim 1. The rejection is premised on the determination that the claim 1 entitled to a priority date of November 17, 2003. However, as discussed in

Section II, claim 1 is entitled to the benefit of the earliest application to which priority is claimed, U.S. provisional application no. 60/041,860, filed April 8, 1997. Because the present claims are entitled to a priority date no later than April 8, 1997, Konety is not prior art.

For at least this reason, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

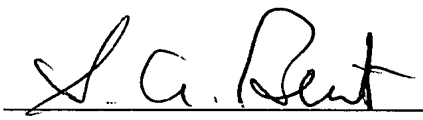
CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned directly, should he believe that any issue warrants further consideration. The Commissioner also is authorized to charge any additional fees, which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extensions of time are needed for timely acceptance of submitted papers, Applicants hereby petition for such extension under 37 CFR §1.136 and authorize payment of any such extensions fees to the deposit account.

Respectfully submitted,

Date April 4, 2007

By 

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